

Thera Care- hand sanitizer gel
Jiangsu Intco Medical Products Co Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

To help decrease bacteria on the skin. Recommended for repeat use.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- Around eyes
- In ears and mouth

- Keep out of eyes. In case of contact, rinse eyes thoroughly with water
- Avoid Contact with broken skin
- Do not inhale or ingest

If irritation or redness develops

If swallowed, get medical help or contact a Poison Control Center right away, 800-222-1222.

Directions

- Wet hands thoroughly with product and allow to dry without wiping
- For children under 6, use only under adult supervision
- Not recommended for infants

Other information

- Store at 68-77°F (20-25°C)
- May discolor some fabrics
- Harmful to wood finishes and plastics

Inactive ingredients

aloe barbadensis extract, carbomer, lemon oil, glycerin, Triethanolamine, water

Package Label - Principal Display Panel



FRONT PANEL



BACK PANEL



FRONT PANEL



BACK PANEL

THERA CARE
hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:7420 1-267
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LEMON OIL (UNII: I9GRO824LL)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74201-267-01	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	03/30/2020	

Labeler - Jiangsu Intco Medical Products Co Ltd (529128686)**Establishment**

Name	Address	ID/FEI	Business Operations
Jiangsu Intco Medical Products Co Ltd		529128686	manufacture(74201-267)

Revised: 4/2020

Jiangsu Intco Medical Products Co Ltd